UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE DAVID EGILMAN'S OPINIONS AND PROPOSED TESTIMONY

July 31, 2019

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INTRODUCTION

Dr. Egilman is a renowned medical doctor qualified to testify as an expert on the causes of the opioid epidemic, including the epidemiological evidence pertaining to those causes, the reasons for the explosive increase in opioid use, and the development of scientific and corporate knowledge of the hazards of opioids. He has reviewed unpublished corporate studies and compared the information available to the scientific community with that available to the companies. This review and comparison requires expertise in medical literature, as well as the unpublished corporate studies and marketing programs. Dr. Egilman has such expertise.

For more than two decades, in more than 300 trials, courts (including Federal Appellate Courts) have determined that Dr. Egilman's expert testimony assists the trier of fact. Over many years, every court but *one* has permitted Dr. Egilman to testify on these and similar matters. Defendants repeatedly cite this single decision, while ignoring the numerous contrary decisions that allowed him to present his opinions.[1] Rather than challenging Dr. Egilman's extensive qualifications and the strength of his opinions, Defendants resort to *ad hominem* attacks and highly selective mischaracterizations of individual opinions, taken out of context. Defendants' complain that Dr. Egilman compares them to the "mafia" and that he has referred to Richard Sackler as "Pablo Escobar," suggesting that such language is too inflammatory to be presented to the trier of fact. But they neglect to mention that it was not Dr. Egilman who made these comments, but rather, in the first instance, Purdue, and in the second, a friend of Sackler's (apparently an anesthesiologist in Illinois), who made the comment *to* Richard Sackler *about* Richard Sackler. Dr. Egilman opines about two internal Purdue documents that portray the company's national sales department ("National

[1] *Newkirk v. ConAgra Foods, Inc.*, 727 F. Supp. 2d 1006 (E.D. Wash, 2010), Defendants' Memorandum ("Def. Mem.") at 3, 8, 9. As discussed more fully below, *Newkirk* had nothing to do with any fact or issue in this case – it involved injuries arising from exposure to diacetyl in microwave popcorn butter flavoring – and another court later admitted Dr. Egilman's nearly identical opinions on the very same issues. *Watson v. Dillon Companies, Inc.*, 797 F. Supp. 2d 1138, 1156 (D. Colo. 2011); *Watson v. Dillon Companies, Inc.*, No. 08-CV-00091-WYD-CBS, 2013 WL 1461500, at *5 (D. Colo. Apr. 10, 2013)

Accounts) as the Sopranos crime family.[2] He also opines about an email to Richard Sackler in 2002 alerting him to a greater need for security for OxyContin supplies, informing him about illegal sales of OxyContin *in a high school*, and telling Sackler "you could become the Pablo Escobar of the new millennium." *Id.* at Ex. B.196.[3] Thus, it was not Dr. Egilman who compared the Defendants to illegal drug dealers, but Purdue and a friend of Richard Sackler. Dr. Egilman's exposure, in his report and potentially at trial, of how Purdue and a friend of Richard Sackler viewed Purdue's business provides no ground for excluding his testimony. Similarly, Defendants attack Dr. Egilman's character, suggesting that he cannot be trusted to provide expert testimony in this case. This attack, too, is baseless. Dr. Egilman has at all times comported himself professionally in this litigation; Defendants do not – and cannot – contend otherwise. He has testified numerous times as an expert witness and courts have found his testimony to be both sound and helpful.

Defendants' motion should be denied in its entirety.

FACTS

Dr. Egilman's Background and Qualifications

Dr. Egilman earned his medical degree at Brown University. After medical school, he completed a residency in internal medicine at the University of Rochester. Following this, he completed NIH's "Epidemiology Training Program." The first year of this program was training at the Harvard School of Public Health where he was awarded a Masters in Public Health (M.P.H.). Dr. Egilman spent the second two years at NIOSH serving as a medical officer. At NIOSH, he was responsible for implementing parts of the OSHA act, and he conducted several epidemiologic studies. He also completed NIOSH's residency in Occupational Medicine. He has published articles on the impact of opioid marketing and FDA policy issues and has testified at FDA hearings on opioid and

[2] The document is a PowerPoint entitled "National Accounts," which portrays a group of men dressed as the mafia Soprano family with the tag line "How you doin'?" Report of David Egilman, MD, Dkt. # 1999-5 at Ex. B.228.

[3] Sackler's response shows him brushing off the concern, and assuming that the drugs being offered were counterfeit. *See* Report of David Egilman, MD, Dkt. # 1999-5 at Ex. B.196.

non-opioid pain medications.[4] In the course of obtaining his M.P.H., Dr. Egilman studied statistics, epidemiology, occupational medicine, warnings and risk communication and regulatory issues. He is board-certified in internal medicine and preventive-occupational medicine. He is Clinical Professor of family medicine at Brown University and teaches a course on topics related to his testimony and has supervised residents in clinical training.

Dr. Egilman ran a clinic for 12 years treating patients and consulting in occupational medicine for large and small companies. He treated patients with opioid medications and relied on manufacture supplied warnings. Dr. David Egilman Dep. (04/25/19), Dkt. # 1961-22 at 119:13-15; Egilman Dep., Dkt. # 1961-23 at 566:13-567:1.

In the more than 30 years since completing his study at Harvard School of Public Health, moreover, Dr. Egilman has become a renowned and recognized expert in numerous areas of medicine and public health. He has developed particular expertise related to warnings and has extensively studied how warnings play a role in preventing illnesses and the current best techniques for providing warnings. Dr. Egilman has published two chapters in the major textbook relating to warning and risk communication.[5] His work on corporate corruption of public health was featured in an article in *Science*, the official journal of the American Association for the Advancement of Science.[6] He has published widely on "medical epistemology," the study of cause-and-effect

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4 Egilman DS, Collins GB, Falender J, Shembo N, Keegan C, Tohan S. The marketing of OxyContin®: A cautionary tale. Indian J Med Ethics. 2019. Accepted for publication; Bohme SR and Egilman DS (2006) A Brief History of Warnings. In M. Wogalter (Ed.). *Handbook of Warnings* (pp. 635-644). Mahwah, NJ: Lawrence Erlbaum Associates; Egilman DS and Schilling JH, Bronchiolitis Obliterans and Consumer Exposure to Butter-flavored Microwave Popcorn: A Case Series, Int J Occup. Environ. Health 18(1):29-42, Jan.-Mar. 2012; Egilman DS and Presler AH, Report of Specific Cardiovascular Outcomes of the ADVANTAGE Trial (Letter), Ann. Intern. Med. 144(10):781, May 16, 2006; Arcoxia FDA hearing, Egilman DS. Testimony at FDA Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on Avandia, Jul 30, 2007. FDA Opioid hearing 2014 Testimony of David Egilman, Impact of Approved Drug Labeling on Chronic Opioid Therapy at 90–91, FDA Canter for Drug Evaluation and Research Public Hearing (Feb. 8, 2013), available at http://www.tvworldwide.com/events/fda/130207/UCM342713.pdf. FDA Opioid hearing, June 12, 2019; https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-11-12-2019-joint-meeting-drug-safety-and-risk-management-advisory-committee-and-anesthetic-and#event-materials.

5 Egilman DS and Bohme SR. (2006). *A Brief History of Warnings*; M. Wogalter (Ed.), *Handbook of Warnings* (pp. 11-20). Mahwah, NJ: Lawrence Erlbaum Associates.

6 Starr, D., Bearing Witness, Science, Jan 25, 2019: 334-337

determinations in medicine; on medical ethics and informed consent; on corporate responsibilities to test products and warn of health hazards. He has testified (twice) before Congress on proper conduct of medical research including study design and informed consent, corporate responsibility to test products and publish study results, consent, and has published peer reviewed papers on these topics. Dr. Egilman has also published, in peer-reviewed, medical journals, on conflicting interests in the context of public health; on techniques used to manipulate scientific studies and scientific articles; and on post-market safety surveillance. (Many of these publications were based in part on review of corporate documents and depositions.) His extensive work on pharmaceutical marketing includes publications concerning FDA-mandated warnings. At Brown, he has taught specifically in the area of FDA drug related warnings and regulations. His letter on "regulatory capture" of the FDA was published in the *Archives of Internal Medicine* in 2007.[7] He published a book chapter that addressed the FDA and pharmaceutical company obligations and interactions.[8]

Dr. Egilman's Report

Based on his broad expertise, Dr. Egilman proposes to offer opinions on a wide range of topics central to this litigation. The first group of opinions represent opinions Dr. Egilman offered in 2004 concerning Purdue. These opinions are concerned primarily with Purdue's fraudulent marketing of OxyContin, the inadequacy of its warnings, and the truth about addiction and pain. The remainder of Dr. Egilman's Report presents the opinions he has formed since 2004. These opinions, too, focus primarily on fraudulent marketing, inadequate warnings, addiction, and pain, but in this context, Dr. Egilman examined documents produced by numerous Defendants and offers opinions

[7] Egilman DS, Presler AH and Valentin CS. *Avoiding the Regulatory Capture of the Food and Drug Administration* (Letter). ARCH OF INTERNAL MED 167(7): 732-733, Apr. 9, 2007.

[8] Egilman DS and Ardolino E. (2010). *The Pharmaceutical Industry, Disease Industry: A Prescription for Illness and Death*. In W.H. Wiist (Ed.), *The Bottom Line or Public Health: Tactics Corporations Use to Influence Health and Health Policy, and What We Can Do to Counter Them*, (pp. 193-224). USA: Oxford University Press;

about all of them. Dr. Egilman also offers certain limited opinions about Defendants' suspicious order monitoring ("SOM") systems, based on his extensive review of internal corporate documents.

Rather than separate the opinion portion of his report from the bases for them, Dr. Egilman presents his opinions in a disaggregated format: each opinion, expressed in a sentence or two or three, is accompanied by a sampling of the source material on which it is based; only after this material has been identified and presented (including through use of screen shots of particular documents that support each opinion) does Dr. Egilman move on to the next opinion, followed by the documentary basis for that opinion, and so on. This format avoids uncertainty about which statements in the Report are "opinions" and which are the facts and bases for the opinions; it also avoids uncertainty about which facts and documents provide the bases for which opinions. Finally, to further aid the fact-finder, Egilman offers a "Capsule of Opinions" that summarizes all of his opinions and organizes the material into seven specific topics.

ARGUMENT

I. DR. EGILMAN IS QUALIFIED TO OFFER HIS OPINIONS

A. Dr. Egilman Is Qualified by Education, Training and Experience to Opine about a Wide-Range of Topics Pertaining to Medicine and the Pharmaceutical Industry

Defendants do not challenge generally Dr. Egilman's qualifications to offer his opinions, even as they mischaracterize the expertise he has.[9] Defendants dismiss Dr. Egilman as an internist who has "essentially stopped practicing medicine."[10] But their focus on Dr. Egilman's residency in internal medicine – completed nearly forty years ago – and the fact that he generally retired from active medical practice at age 65, ignores entirely his distinguished career as a clinician, a public health practitioner and academic, an occupational physician, an epidemiologist, an expert on research misconduct and

[9] Defendants do contend that Dr. Egilman is unqualified to offer opinions in particular areas; those arguments are addressed below.

[10] Def. Mem. at 4.

warnings, and the marketing of toxic pharmaceuticals, subjects in which he teaches or has taught courses at the Alpert School of Medicine at Brown University and has published numerous peer-reviewed articles.[11]

Given the breadth and depth of Dr. Egilman's expertise and qualifications, it is not surprising that, while Defendants *imply* that Dr. Egilman lacks the requisite expertise to offer his opinions, they stop short of actually arguing that he is not qualified.[12] Nor could they make such an argument. Rule 702 requires that an expert be qualified by virtue of his "knowledge, skill, experience, training, or education." Fed. R. Evid. 702; see also *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881 (5th Cir. 2013); *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999). Thus, the rule expressly provides that a witness's expertise is not limited to subjects in which he or she has received formal education or training, but includes subjects in which the expert has knowledge, skill, or experience. *See also United States v. Hernandez-Palacios*, 838 F.2d 1346, 1350 (5th Cir. 1988). Moreover, numerous courts recognize that, as the First Circuit has held, "[t]he fact that the physician is not a specialist in the field in which he is giving his opinion affects not the admissibility of his opinion but the weight the jury may place on it." *Mitchell v. United States*, 141 F.3d 8, 15 (1st Cir. 1998), *accord In re Heparin Products Liab. Litig.*, 803 F. Supp. 2d 712, 747 (N.D. Ohio 2011, *aff'd sub nom. Rodrigues v. Baxter Healthcare Corp.*, 567 F. App'x 359 (6th Cir. 2014); *Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion*, 345 F.3d 15, 24 (1st Cir. 2003); *see also McDowell v. Brown*, 392 F.3d 1283, 1297 (11th Cir. 2004) (same); *United States v. Garcia*, 7 F.3d 885, 890 (9th Cir.1993); *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991); *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2nd Cir. 1995); *Huss v. Gayden*, 571

[11] Dr. Egilman's Background and Qualifications are summarized above. The Report also sets out his background, including his education, licensure, medical practice, courses he has taught, book chapters and articles he has written, congressional testimony and presentations he has given, and awards he has won. *See* Egilman Rep., Dkt. #1999-5, at 29-36.

[12] Defendants disparage the breadth of Dr. Egilman's expertise, contending that he "believes himself to be" an expert in a wide range of fields. *See* Def. Mem. at 4 n.8. Dr. Egilman teaches and has published in each of these issues and has been qualified to provide expert testimony in all of them. These are all subject matter of the study and practice of public health.

F.3d 442, 455 (5th Cir. 2009); *In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Products Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, *8 (S.D. Ill. Dec. 16, 2011).

B. Dr. Egilman's Expert Opinions Have Been Accepted by Numerous Federal and State Courts

In light of his credentials and experience, it is not surprising that Dr. Egilman's expert opinions on a variety of topics have been accepted by numerous courts. *See, e.g., DePuy Orthopaedics,* 2016 WL 6271474, at *6-7 (rejecting contention that Dr. Egilman's opinions were subjective personal opinion and the result of personal bias, and finding him qualified to offer opinions about research design and interpretation, regulatory requirements, and marketing of medical information, including medical warnings); *Stults*, *slip op.*; *Kuiper*, 602 F. Supp. 2d at 1050; *Watson v. Dillon Companies, Inc.*, 797 F. Supp. 2d 1138, 1156 (D. Colo. 2011); *Watson v. Dillon Companies, Inc.*, No. 08-CV-00091-WYD-CBS, 2013 WL 1461500, at *5 (D. Colo. Apr. 10, 2013); *Dunn v. Owens-Corning Fiberglass*, 774 F. Supp. 929, 942 (D.V.I. 1991), *aff'd in pertinent part sub nom. Dunn v. HOVIC*, 1 F.3d 1362 (3d Cir. 1993*), modified on other grounds*, 13 F.3d 58 (3d Cir. 1993), *and vacated in part on other grounds sub nom. Dunn v. HOVIC,* 1 F.3d 1371 (3d Cir. 1993,), *modified,* 13 F.3d 58 (3d Cir. 1993); *Bush v. Eaton Corp.*, No. 10-CI-504, *slip op.* (Ky. Cir. Ct. Oct. 7, 2011); *Pittsburgh Corning Corp. v. Walters*, 1 S.W.3d 759 (Tex. App. 1999) (noting in particular, Dr. Egilman's expertise with medical literature); *Hall v. Babcock & Wilcox Co.*, 69 F. Supp. 2d 716 (W.D. Pa. 1999); *Kinsey v. Owens-Corning,* et al., IP 90-1362-C M/S, *slip op.* (S.D. Ind. Oct. 28, 1997); *Owens-Corning Fiberglas Corp. v. Stone*, No 03-94-00449-CV, 1996 WL 397435 (Tex. App. July 17, 1996).

Notably, in *Kuiper*, the defendant argued, much as Defendants here do, that Dr. Egilman's opinions should be excluded because he was a "zealous advocate for his own personal agenda" and not a proper objective expert. The court rejected this challenge, and held that Dr. Egilman's opinions were admissible. It noted that "the court cannot ignore the fact that Dr. Egilman is a physician, with a Masters degree in public health, who is board certified in internal and occupational medicine with a

specialty in occupational lung disease, has published dozens of articles over a wide array of health topics, and has been qualified to testify in numerous state and federal courts in the United States." 602 F. Supp. 2d at 1051. *See also DePuy Orthopaedics,* 2016 WL 6271474, at *7.

Omitting to mention the decisions in which Dr. Egilman has been qualified to testify as an expert, Defendants cite the single decision where Dr. Egliman's testimony was excluded, *see* Def. Mem. at 3,8,9, *citing Newkirk v. Conagra Food, Inc.,* 727 F. Supp. 2d 1006 (E.D. Wash. 2010) *aff'd*, 438 F. App'x 607 (9th Cir. 2011)[13] But *Newkirk* is inapplicable here. *Newkirk* involved injuries arising from exposure to the chemical diacetyl used in microwave popcorn butter flavoring, which exposures can cause serious, sometimes fatal, lung disease. The court in that case did not find adequate data in the record presented to support Dr. Egilman's opinion that vapors emitted from microwaving a popcorn bag were comparable to exposures of quality control workers popping microwave popcorn and mixers of butter flavoring. The situation in *Newkirk* bears no resemblance to this case, where Dr. Egilman's opinions are carefully grounded in the specific documentary record.

Moreover, the opinions of Dr. Egilman that that were excluded in *Newkirk* were nearly identical to those subsequently held to be admissible by two different judges. See *Watson v. Dillon Companies, Inc.*, 797 F. Supp. 2d 1138, 1156 (D. Colo. 2011); *Watson v. Dillon Companies, Inc.*, No. 08-CV-00091-WYD-CBS, 2013 WL 1461500, at *5 (D. Colo. Apr. 10, 2013).

Rather than suggest that Dr. Egilman lacks the qualifications to offer his opinions, Defendants argue instead that Dr. Egilman is unfit to testify by reason of his character, relying on cases from 12 and 18 years ago. It is true that, twelve years ago, Dr. Egilman was found to have violated a case management order. *See In re Zyprexa Injunction*, 474 F. Supp. 2d 385 (E.D.N.Y. 2007), *aff'd sub nom. Eli Lilly & Co. v. Gottstein*, 617 F.3d 186, 192 (2d Cir. 2010). But although he has been

[13] In their discussion of the *Newkirk* decision, Defendants imply that other courts have excluded Dr. Egilman's testimony, but that is not the case. One of the cases Defendants cite in that discussion is *Lane,* discussed above, where Dr. Egilman testified at the bequest of a defendant asbestos manufacturer. Def. Mem.at 3.

qualified, and has testified, numerous times since then, he has been neither accused of, nor found to have engaged in, any improper conduct since that time. Defendants offer no sound argument why this incident from 12 years ago – which has nothing whatsoever to do with the soundness of the opinions being offered here -- should preclude Dr. Egilman's testimony now. Indeed, courts that have found Dr. Egilman's opinions admissible since 2007 have not found the *Zyprexa* incident disabling. Defendants' other case is even older and less relevant. In 2001, Dr Egilman was falsely accused of posting confidential documents on the Internet. *Ballinger v. Brush Wellman Inc.*, No. 96-CV-2532, 2001 WL 36034524 (Colo. Dist. Ct. June 22, 2001), *aff'd in part, vac'd in part sub nom. Egilman v. District Court,*, 01-CA-1992, *slip op.* (Colo. Ct. App. Sept. 5, 2002). In fact, the defendants' lawyers had illegally hacked Dr. Egilman's computer, downloaded pages that had been on his private site (nothing was posted on the public Web) – and then claimed they had retrieved them from a public site. Defendants omit this history, including the fact that the offending attorney was subsequently sanctioned.

II. DR. EGILMAN'S OPINIONS ARE RELIABLE

A. Dr. Egilman's Opinions Are Grounded in a Reliable Methodology

Dr. Egilman's assignment was to determine within a reasonable degree of medical and scientific certainty whether or not various defendants, working together or separately, contributed to causing the opioid epidemic. Egilman Dep., Dkt. 1961-22 at 23:3-8. With respect to the formation of his individual opinions, he testified that "the overriding question is the assignment. So all of these [opinions] are subanswers to the assignment question." Egilman Dep., Dkt. 1961-22 at 243:13-15. He further testified that, "in science [sic] use a null hypothesis, which implies a non-causal relationship between two items." Egilman Dep., Dkt. 1961-22 at 234:18-20. Thus, for each individual opinion, Dr. Egilman's approach was to test the hypothesis that various defendants, working together or

separately, did *not* contribute to causing the opioid epidemic.[14] Of course, even a single piece of evidence contradicting the hypothesis is sufficient to disprove it; Dr. Egilman found numerous examples disproving the hypothesis, often in the form of a single document, which he sets forth in the individual opinions in the Report.

Defendants claim that Dr. Egilman's opinions are not reliable because, they assert, his methodology is unreliable and cannot be replicated. They further claim that Dr. Egilman "cannot explain the particular mechanics" of his methods.[15] Defendants ignore the thorough discussion in the Report and mischaracterize Dr. Egilman's testimony. The Report devotes approximately 14 pages to a description of methodologies Dr. Egilman employed, which are both scientific and reliable. Egilman Rep., Dkt. # 1999-5 at 37-50. The Report shows that Dr. Egilman reviewed massive amounts of information, both from Defendants' own files and from scientific studies.[16] He consulted medical literature and textbooks, reviewed depositions of experts and corporate officials, and performed his own searches within the production of documents made by Defendants. *Id.* To form his opinions, he applied his knowledge, expertise, and experience as a medical doctor, an epidemiologist, a researcher, and an academic with specific expertise in medical warnings, regulations, and corporate conduct to this information. Although Defendants claim to be perplexed by the two approaches Dr. Egilman used in formulating his opinions – the grounded theory and evidence-based medicine methods – both methods are thoroughly explained and well-supported by citation in the Report.

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[14] Dr. Egilman's reference to use of the null hypothesis refers to the classic approach described by Sir Karl Popper, who explained that evidence consistent with such a null hypothesis cannot prove that it is always true, but even a single piece of evidence contradicting it will be sufficient to disprove it. In Sir Karl's famous example, the null hypothesis is: All swans are white. Counting 1,000 white swans does not prove that all swans are white, but finding a single black swan is proof that they are not all white. Popper, K. Conjectures and Refutation, Routledge, London, 1963 at 22.

[15] Def. Mem. at 6.

[16] Defendants' imply that Dr. Egilman claims to have read every single document produced by Defendants, totaling hundreds of millions of pages. Def. Mem. at 5. This is not so. Dr. Egilman explained, both in the Report and at his deposition, that he used search processes to go through the documents, and in this way "considered" the entire database. Egilman Rep., Dkt. # 1999-5 at 37-50; Egilman Dep., Dkt. # 1961-22 at 138:23-139:15, 265:12-22.

With respect to the grounded theory approach, which incorporates the review of litigation documents and relevant scientific literature, Dr. Egilman cites to four peer-reviewed papers on the method that he co-authored. Egilman Rep., Dkt. #1999-5 at 39. His discussion of the evidence-based medicine method similarly sets out the precise steps and guidelines for this approach in detail, including citation to peer-reviewed articles. *Id.* at 40-50. Based on these approaches, for each opinion offered in his Report, Dr. Egilman provides an explication of the basis of the opinion, with citation, quotation, and/or reproduction of relevant portions of Defendants' own documents. Opinions so thoroughly grounded in the facts as reflected in Defendants' own documents are methodologically sound.

Lacking any other way to address Dr. Egilman's sound approach, Defendants assert, without basis, that his methods "reside strictly in Egilman's mind." Def. Mem. at 6. They resort to their usual assertion that Dr. Egilman "cherry-picked" documents and assert, without support, that Dr. Egilman "came to his conclusions first" and used the cherry-picked documents to support the opinion he had already formed.[17] This is baseless. The Report describes Dr. Egilman's methods and demonstrates that he used Defendants' own documents to draw conclusions about what they knew and did. His opinions for the most part are tied directly to one or more of Defendants' own documents.[18] Thus, it makes no sense that Dr. Egilman would form an opinion and then search through millions of pages of documents to find those documents that supported it; rather, of course, he used the methodologies he described to search and locate documents that show what Defendants knew or did, and then formed his opinions based on them, which is a reliable methodology. *See Cook v. Rockwell Intern. Corp.*,

[17] Defendants cite several cases for the general proposition that this kind of "result-driven analysis" is inappropriate, including *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 892 F.3d 624, 634 (4th Cir. 2018). Def. Mem. at 7. Of course, neither *In re Lipitor* nor any of the other cited cases involved or have any applicability to Dr. Egilman.

[18] Defendants criticize Dr. Egilman for basing certain opinions on "a single document." Def. Mem. at 7. But that is hardly surprising: numerous documents contain statements or describe activities that by themselves show what Defendants knew or did and can thus be the basis of an opinion.

580 F. Supp.2d 1071, 1106-07 (D. Colo. 2006) (rejecting defendants' argument that plaintiffs' expert relied on limited documents where expert identified exhaustive search he and his assistants performed and finding such search method reliable).

The cases cited by Defendants in support of their contention that Dr. Egilman's opinions lack a sound methodology are inapposite. Defendants cite *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244 (6th Cir. 2001) for the proposition that expert testimony "that is connected to existing data only by the ipse dixit of the expert" should be excluded. *Id.* at 254. But that is not the case here. Dr. Egilman's Report clearly and carefully ties his opinions to the documents he has reviewed and cited. There is no "analytical gap" between the documents and Dr. Egilman's opinions. *Id.* Defendants simply so state, choosing to ignore that Dr. Egilman's opinions directly address and are rooted in their own documentation. Similarly, in *Numatics, Inc. v. Balluf, Inc.,* 66 F. Supp. 3d 934 (E.D. Mich. 2014), as Defendants note, the expert overly relied on counsel for analysis and did not tie his experience to his opinions. *Id.* at 941-42. In fact, the court characterized the expert as "the most problematic" and explained that the deficiencies "stem from the fact that [the expert] did not draft his own report," which the court found to be a "remarkable breach of ethics and protocol." *Id.* at 941. Neither of those issues occurred here, as Dr. Egilman did not rely on counsel for his analysis, and he directly tied his opinions to his substantial education and expertise.

B. Dr. Egilman's Personal Views Are Matters for Cross-Examination

Defendants' opening paragraphs label Dr. Egilman a mere plaintiffs' "mouthpiece" and "a zealous and partisan crusader" with an anti-corporate bias.[19] As numerous courts have found, however, even if Dr. Egilman had such a view of pharmaceutical corporations, "[w]hether and, if so, the extent to which an expert's philosophical bent biases her review is a credibility determination that has always been within the province of the jury." *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1335

[19] Def. Mem. at 2,3.

(11th Cir. 2014); *see also In re: DePuy Orthopaedics, Inc.*, No. 3:11-MD-2244-K, 2016 WL 6271474, at *7 (N.D. Tex. Jan. 5, 2016) ("To the extent Defendants contend that Dr. Egilman has a bias against corporations, Defendants, corporate defendants, or the products at issue, it implicates the weight, not admissibility of the testimony"); *DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000); *Cruz-Vazquez v. Mennonite Gen. Hosp., Inc.*, 613 F.3d 54, 59 (1st Cir. 2010). In any event, Defendants present an incomplete and misleading picture of this issue. One of the cases Defendants cite to illustrate how courts have addressed Dr. Egilman's purported zealotry is *Lane v. Gasket Holding, Inc.*, No. B153966, 2003 WL 21666623 (Cal. App. Jul. 17, 2003),[20] in which Dr. Egilman testified at the request of the *defendant corporation*, Gasket Holdings, an asbestos manufacturer, against the individual plaintiff. Defendants fail to note this critical fact, which of course does not support their effort to paint him as having an anti-corporate bias.[21]

C. Dr. Egilman's References to the "Venture" Do Not Preclude Admission of His Opinions

Defendants purposefully and repeatedly misconstrue Dr. Egilman's use of the term "Venture" in the Report. Dr. Egilman explicitly defines the term in the Definitions section of the Report: it "refers to all Defendants in the Opiate Litigation (including their associated individuals and/or organizations) acting in concerted fashion separately or together to effect a particular objective." Egilman Rep., Dkt. #1999-5 at 51. This definition further references Exhibit B.473, which provides certain bases for the reference to the "Venture." Thus, the term is not some ill-defined mystery, as Defendants suggest. Moreover, as Defendants are well aware, Federal and Ohio RICO claims, as well as a conspiracy claims, have been asserted against Defendants here, and are subject to pending motions for summary judgment by both the manufacturing and distributor defendants. Thus, while in many instances, Dr. Egilman's opinions are based on the actions or knowledge of a single defendant, under

[20] *Id.* at 3.

[21] In any event, as discussed below, the extent to which an expert's philosophy biases his or her opinion goes to the weight, not the admissibility of the testimony.

the asserted RICO and conspiracy claims, such actions or knowledge could be inferred to other defendants, regardless of whether they are directly implicated by the underlying documentation supporting the opinion. This is the clear import of Dr. Egilman's opinion with regard to the "Venture." Of course, if the Court dismisses or otherwise limits the RICO or conspiracy claims asserted by Plaintiffs, then Dr. Egilman's opinions would still be viable against the defendant or defendants implicated by the specific opinion.[22]

Nor, in any event, is the terminology central to Dr. Egilman's opinions. If the Court finds that use of the term "Venture" would not be helpful to the trier of fact, Dr. Egilman can offer all of the opinions in his Report at trial without use of that particular term.

D. Dr. Egilman's Testimony about What Defendants Knew Is Not Improper Speculation about Defendants' State of Mind

Defendants argue that Dr. Egilman's opinions include improper testimony about Defendants' motive, intent or state of mind. They cite to *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531 (S.D.N.Y. 2004), a case that did not involve Dr. Egilman, and seek to ascribe the experts' opinions there to those of Dr. Egilman here.[23] But Dr. Egilman does not and will not opine about "the motive, intent, and state of mind" or "alleged failures" of the Defendants. *Id.* at 539. Once again, Defendants have conflated testimony about what Defendants actually *knew* (or did or did not do) based on documentary evidence establishing such knowledge or actions, with testimony about subjective states of intent. In this case Dr. Egilman only addresses information that the defendants had in their possession or should have known based on available medical information. He does not opine about what the defendants actually "knew."

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[22] By way of example, Defendants complain about Opinion B.71 because it uses the term "Venture," maintaining that Dr. Egilman is claiming that the actions described in the opinion's supporting document, an internal Purdue document, were undertaken by all Defendants. Def. Mem. at 8. Of course, the document itself only implicates Purdue, but, as noted, under the theory and definition of the "Venture," if it is held that the actions of one defendant implicate more or all of them, then this Opinion so applies as well.

[23] Def. Mem. at 9.

In a diacetyl case, defendants sought to exclude Dr. Egilman's testimony about what the defendants "knew or should have known" about the dangers of diacetyl (the disease-causing chemical in butter-flavored microwave popcorn vapors). The court denied the motion, holding that "[t]o the extent that an expert adequately demonstrates a basis for an opinion about what the defendants knew or should have known from such information that was within the defendants' possession, then such an opinion may be admissible at trial. . . ." *Stults*, slip op. at 8. The same is true here. *See also Dunn v. Owens-Corning Fiberglass*, 774 F. Supp. 929, 942 (D.V.I. 1991), *aff'd in pertinent part sub nom. Dunn v. HOVIC*, 1 F.3d 1362 (3d Cir. 1993*), modified on other grounds*, 13 F.3d 58 (3d Cir. 1993), *and vacated in part on other grounds sub nom. Dunn v. HOVIC,* 1 F.3d 1371 (3d Cir. 1993), *modified,* 13 F.3d 58 (3d Cir. 1993) (Dr. Egilman permitted to testify regarding what an asbestos company knew or should have known about the risks of asbestos)

Thus, while Defendants complain about Dr. Egilman's opinions concerning Defendants' knowledge and actions, the documents he cites reflect precisely such knowledge and actions. By way of example, opinion B.193 states that "Rebates increase profits and sales and were used to influence pharmacists." In support of that opinion, Exhibit B.193 cites PDD8801142702 and includes a screenshot of the document, which is an email from Phil Cramer. Mr. Cramer states that "Lynn Sipe uses the rebate in a unique way. He tells the pharmacist that they will realize an additional $70 profit on their first prescription of the 80mg. While this may seem like a slight variation from presenting the rebate, it gets the pharmacist to focus on the business impact and the effect on their bottom line." Egilman Rep., Dkt. # 1999-5 at Exhibit B.193. Similarly, in opinion B.479, Dr. Egilman opines that "CVS's suspicious order monitoring system did not monitor suspicious orders. It's SOM policy specified that if multiple orders for the same store are flagged during the same month, all orders after the first order will NOT be investigated and will be automatically released based on the release of the first order." Exhibit B.479 cites CVS-MDLT1-000083064, which states exactly that: "if order is

cleared on 1st of month and cleared, and store then orders again that month it won't be looked at a. If system flags it, we are required to look at it and document why it was released, currently we are simply releasing order based on past due diligence on a different order…" Egilman Rep., Dkt. # 1999-5 at Exhibit B.479. Dr. Egilman is reporting on the very information set forth in the documents, not reflecting on Defendants' state of mind or motive. To say that Defendants "knew" or "said" or "did" something is merely a descriptive account of the information contained in the document. Dr. Egilman is not ascribing intentions, motives or state of mind to Defendants; he is simply describing what the documents say.[24]

E. Dr. Egilman's Testimony about Warnings and Labeling Is Proper

Defendants similarly conflate testimony about corporate conduct and intent. They claim that Dr. Egilman is not qualified to opine on "corporate conduct," including warnings and regulatory conduct and then cite cases in support of the notion that an expert cannot opine on "corporate intent." Def. Mem. at 11-12. But, again, that is not what Dr. Egilman is doing.

First, as outlined above, Dr. Egilman is a recognized expert in numerous areas of medicine, including corporate responsibilities to test products and warn of health hazards. He has testified before Congress (twice) on corporate responsibilities and has published in peer-reviewed medical journals on these topics. He has studied the specific subject of medical warnings, including their history and efficacy, and has published several papers and two textbook chapters on warnings. He has taught about warnings for over 20 years at the medical school at Brown University, and teaches residents in Family Medicine on warnings and risk communication in the clinical setting. He has published on post-market safety surveillance and pharmaceutical marketing, as well as on FDA-mandated warnings. In short, he is clearly qualified to offer opinions on warnings, regulatory matters, and FDA requirements and communications.

[24] Of course, to the extent that any particular opinion of statement of Dr. Egilman's does go beyond reporting on what a document says, that particular statement could be excluded without excluding the entirety of Dr. Egilman's opinion.

Defendants do not address Dr. Egilman's extensive and relevant qualifications. They merely assert that he is "unqualified" to opine in these areas, Def. Mem. at 12, and claim, without citation, that it "does not matter" that he has taught or written on the subject of warnings. *Id.* at 13. They parade a list of facts that do not amount to grounds to disallow Dr. Egilman's testimony, including that Dr. Egilman admits that he has not worked with the FDA on a new drug application, never worked with DDMAC, never consulted with the FTC, and never worked for a pharmaceutical company. *Id.* Finally, because they have nothing else to rely on, Defendants cite to cases that affirm the obvious – an expert who is unqualified to testify on regulatory issues may not do so. *Id.* at 12. These cases are inapposite. Dr. Egilman is highly qualified to address these issues and should be permitted to do so. Indeed, Defendants do not cite a single case excluding Dr. Egilman from testifying regulatory/warning matters. And as noted above, he has been allowed in numerous state and federal courts, including with respect to regulatory/warning matters.

F. Dr. Egilman Does Not Offer Improper Legal or Ethical Conclusions

Defendants assert that Dr. Egilman proposes to testify about Defendants' "ethical or legal obligations." Def. Mem. at 14. That is not true, and the examples Defendants cite do not constitute "legal or ethical conclusions" and do not warrant exclusion. For example, Defendants' assert that Dr. Egilman's opinion concerning whether FDA-mandated warning labels in the Physician's Desk Reference (PDR) should be updated for all drugs for every year that they were sold constitutes a legal opinion. However, this is a regulatory – and public health – opinion, not a legal opinion. It is (or should be) undisputed that expert testimony in regulatory areas can be helpful to a jury and is admissible. *In re Yasmin and YAZ,* 2011 WL 6302287, *12 (testimony of expert in FDA regulations permitted, because it would "assist the trier of fact in understanding the federal regulations"; jury can be instructed that Court, not expert, provides law governing the case); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D. N.Y. 2009) (lay jury cannot be expected to understand

complex regulatory framework without testimony from expert). Such testimony raises concerns only when an expert seeks to opine about the law applicable to the case. *Fosamax,* 645 F. Supp. 2d at 191 n.16. That is not the situation here, and Dr. Egilman can offer valuable guidance to the jury on the scope and application of FDA regulations.

Defendants' two other examples of Dr. Egilman's purported "ethical" or "legal" conclusions are similarly off point. Def. Mem. at 14. An opinion about training physicians on proper disposal of opioids is neither a "legal" nor an "ethical" opinion, but rather an opinion about medical practice within the realm of Dr. Egilman's public health expertise. And Dr. Egilman's statement that Purdue destroyed documents is a factual statement, not a legal or ethical one, based on the internal email cited. As with testimony about regulatory issues, the jury can be instructed that the Court, not the expert, provides the law governing the case.

Dr. Egilman does not intend to and will not offer legal or ethical concerns. Defendants' claims in this regard have no merit.

III. DR. EGILMAN'S TESTIMONY WILL ASSIST THE TRIER OF FACT

Dr. Egilman's knowledge of various matters central to this case will assist the jury in determining the facts. *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981) ("Under the Federal Rules of Evidence, the only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth."). Dr. Egilman's testimony will assist the jury in determining the facts of the case in numerous respects, including:

- Dr. Egilman will compare the information available to the medical community in published literature to that available to the FDA and Defendants. This requires knowledge of the published medical literature that is only available to a medical expert who has reviewed documents and testimony from all three sources.
- Dr. Egilman will explain how physicians obtain information on drug risks and benefits after graduation from medical school. This requires specialized expertise and experience which Dr. Egilman has as a medical school faculty

member and practicing physician. He has also published on these issues, as set forth above.

- Dr. Egilman will describe the molecular mechanisms that explain how pain medications treat pain and how they cause adverse health effects, including addiction. This requires medical expertise.
- Dr. Egilman will compare the information provided in marketing information with the information on efficacy and side effects available in corporate documents and medical literature. Having an expert in pharmaceutical marketing will assist the trier of fact.
- Dr. Egilman will explain Defendants' use of third party entities, including Front Groups and Continuing Medical Education. Again, as a marketing expert, his testimony will assist the trier of fact.

Dr. Egilman's testimony will be of particular help to the trier of fact because he is able to summarize and explain voluminous materials. *See* Fed. R. Evid. 611; *United States v. Swanquist*, 161 F.3d 1064, 1072-73 (7th Cir. 1998) ("The proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court."); *In re: DePuy Orthopaedics, Inc* 2016 WL 6271474, *7 (where documents and other information expert reviewed are complicated, voluminous, or involve scientific or technical data, expert narrative testimony may assist the trier of fact in understanding the documents).

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion to exclude Dr. Egilman's testimony in its entirety.

Dated: July 31, 2019

Respectfully submitted,

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